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Congress of the United States

House of Representatives

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MEMORANDUM

To: Members of the Subcommittee on National Security, Emerging Threats, and International Relations

From: Christopher Shays
Chairman

Date: June 9, 2005

Subject: Briefing memo for the June 14, 2005 Subcommittee hearing

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Attached find the briefing memo required by Committee rules for the hearing on Tuesday, June 14, 2005 entitled, *Elusive Antidotes: Progress Developing Chemical Biological Radiological and Nuclear (CBRN) Countermeasures.*
The hearing will convene at 2:00 p.m. in room 2247 Rayburn House Office Building.

June 9, 2005

MEMORANDUM

To: Members of the Subcommittee on National Security, Emerging Threats, and International Relations

From: Kristine K. Fiorentino, Professional Staff Member KF

Subject: Briefing memorandum for the hearing *Elusive Antidotes: Progress Developing Chemical Biological Radiological and Nuclear (CBRN) Countermeasures*, scheduled for Tuesday, June 14, 2005, at 2:00 p.m. in room 2154 Rayburn House Office Building in Washington D.C.

PURPOSE OF THE HEARING:

The purpose of the hearing is to examine the interagency process used to develop medical countermeasures to CBRN weapons, and how that process is linked to validated threats. The hearing will examine the efficiency and effectiveness of steps to identify, evaluate, prioritize and acquire countermeasures.

HEARING ISSUES:

1. **How are medical countermeasures to CBRN weapons developed?**

2. **How is this process linked to validated threats?**

BACKGROUND

It has been almost four years since the anthrax attacks on Capitol Hill. Since this time the federal government has taken steps to develop medical countermeasures to chemical, biological, radiological and nuclear (CBRN) weapons. However the success of these steps will depend on the cooperation between various agencies and the private sector.

National Institute of Allergy and Infectious Diseases (NIAID)

The National Institute of Allergy and Infectious Diseases (NIAID) is a component of the National Institutes of Health (NIH) which supports research related to organisms likely to be used as biological weapons as well as research on other infectious diseases.

In October 2004, NIAID announced it had four new biodefense contracts totaling $232 million for vaccine development against smallpox, plague and tularemia. Included in these contracts was one with DynPort Vaccine Company LLC to modify an existing contract to include the manufacture of a pilot batch of live, attenuated tularemia vaccine. **(Web Resource 1)**

NIAID has set research priorities and goals for potential bioterror threats with particular emphasis on "Category A" agents. The Centers for Disease Control and Prevention (CDC) has defined Category A agents as those that, "can be easily disseminated or transmitted from person to person; result in high mortality rates and have the potential for a major public health impact; cause public panic and social disruption; and require special action for public health preparedness." **(Web Resource 2)** Category A agents include anthrax, botulism, plague, smallpox, tularemia, and viral hemorrhagic fevers.

Category B agents are the second highest priority agents for CDC and are, "moderately easy to disseminate; result in moderate morbidity rates and low mortality rates; and require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance." **(Web Resource 2)** Category B agents include Q fever, ricin toxin, brucellosis, viral encephalitis, water safety threats and food safety threats along with other diseases.

Category C agents are the third highest priority agents and they include, "emerging pathogens that could be engineered for mass dissemination in the future because of availability; ease of production and dissemination; and have a potential for high morbidity and mortality rates and major health impact." **(Web Resource 2)** These agents include nipah virus and hantavirus. **(Web Resource 2)**

NIAID recently awarded 10 grants and 2 contracts totaling $27 million to fund development of new therapeutics and vaccines against Category A agents. These are the first awards made by NIAID using authorities provided by Project BioShield. These grants and contracts range in length from 12 to 18 months. Included in these contracts was one for DVC Dynport LLC for the development and production of antibodies that protect against botulinum toxin type E. **(Web Resource 3)**

Chemical Biological Medical Systems Joint Project Management Office

The Department of Defense Chemical Biological Medical Systems Joint Project Management Office (CBMS-JPMO) is responsible for "the development, procurement, fielding, and sustaining of premier medical protection and treatment capabilities against chemical and biological warfare agents." **(Web Resource 4)** The products are submitted through the U.S. Food and Drug Administration (FDA) licensing or approval processes. The CBMS-JPMO is comprised of two Joint Product Management Offices: the Joint Vaccine Acquisition Program (JVAP) and the Medical Identification and Treatment Systems (MITS). **(Web Resource 4)**

The JVAP was established in 1996 to, "manage the advanced development and licensure of candidate vaccines by a prime systems contractor." **(Attachment 1, p. 29)** The mission of the Department of Defense Joint Vaccine Acquisition Program (JVAP) is to "develop, produce and stockpile FDA licensed vaccine products to protect the war fighter against biological warfare agents." **(Web Resource 7)**

The Department of Defense awarded a $322 million contract in 1997 to DynPort Vaccine Company to develop, license, and store vaccines to immunize 300,000 troops against smallpox, tularemia and other microbes. The DynPort contract is for the production of tularemia vaccine, vaccinia vaccine (smallpox vaccine), Q-fever vaccine, and two other products.

The Medical Identification and Treatment Systems (MITS)

The Medical Identification and Treatment Systems (MITS) centrally manages the development, acquisition and fielding of products used for the prophylaxis, treatment, and diagnosis of chemical and biological warfare agent exposure in U.S. Service members. MITS products range from specific hardware devices which will enable medical personnel to diagnose specific biological warfare agent exposure, to drugs which will prevent or mitigate the actions of chemical or biological agents. **(Web Resource 7)**

Institute of Medicine report

The Institute of Medicine 2004 report entitled, "Giving Full Measure to Countermeasures: Addressing Problems in the DOD Program to Develop Medical Countermeasures Against Biological Warfare Agents" examined the DOD biowarfare countermeasure drug and vaccine acquisition process.

The IOM found, "The biodefense efforts of the Department of Defense (DoD) are poorly organized to develop and license vaccines, therapeutic drugs, and antitoxins to protect members of the armed forces against biological warfare agents." **(Attachment 1, p. 1)**

The report states:

> The committee sees dismal prospects for successful results (and no prospects for faster results) from the current efforts by DoD's Chemical and Biological Defense Program to produce medical biodefense countermeasures. This task has not been given sufficient priority by DoD to produce the intended results. Further more, the disjointed and ineffective management and inadequate funding of current efforts are clear indications that DoD leaders lack an adequate grasp of the commitment, time scientific expertise, organizational structure and financial resource required for success in developing vaccine and other pharmaceutical products. Developing these products is a difficult endeavor, even with strong leadership and adequate resources. The fragmented half-measures of DoD's current effort cannot be expected to succeed. **(Attachment 1, p. 4)**

The IOM report recommends the Secretary of Defense and Congress make the development of medical countermeasures a priority, establish a sound infrastructure to support the program and address other challenges related to the development of medical countermeasures. **(Attachment 1, p. 5)** Specifically the IOM believes "Congress should authorize the creation of the Medical Biodefense Agency, a new DoD agency responsible for the research and development program for medical countermeasures against biological warfare agents." **(Attachment 1, p. 13)**

The report also recommends an external review committee of experts in the development of vaccines and drugs be established to review and evaluate the program and performance of the DOD research and development program. IOM further recommends if after three years, the review committee finds the DOD research and development program for medical bidefense countermeasures has not made sufficient progress, the program be transferred from DOD and moved to an agency responsible for promoting the development of medical countermeasures for bioterrorism defense such as NIH. **(Attachment 1, pp. 13-14)**

Project BioShield

The Project BioShield Act of 2004, Public Law 108-276, was signed into law by President Bush on July 21, 2004. This law authorizes $5.6 billion over 10 years for the government to purchase and stockpile medical countermeasures to protect against a chemical, biological, radiological, or nuclear (CBRN) attack. **(Web Resource 5)**

Under BioShield, the Secretary of Homeland Security and the Secretary of Health and Human Services are responsible for working together to evaluate threats, and support research and funding for medical countermeasures. **(Web Resource 6)**

The Office of Research and Development Coordination (ORDC) under HHS is responsible for handling Project BioShield Procurement activities and other public health emergencies. Procurement awards made under Project BioShield include a $122.7 million contract awarded to BioPort Corporation for the manufacture and delivery of 5 million doses of Anthrax Vaccine Adsorbed (AVA), a licensed anthrax vaccine; a $5.7 million contract to Fleming and Company for the manufacture and delivery of 1.7 million pediatric doses of liquid potassium iodide; and a $877.5

million contract to VaxGen, Inc. to manufacture and deliver 75 million doses of a new anthrax vaccine. **(Web Resource 7)**

DISCUSSION OF HEARING ISSUES

1. How are medical countermeasures to CBRN weapons developed?

The development of medical countermeasures to CBRN weapons is a difficult, lengthy, expensive and risky venture. Since there is not a commercial market for these products, many companies have decided not to get involved in producing countermeasures. Those companies who decide to get involved may face several hurdles and difficulties and may be turned off by the process or from a lack of commitment on the part of the government to back their product.

It is difficult for the biodefense industry to know what the needs of the government are and how they can best fulfill those needs. The list of potential threats is long and industry complains the government has not made the ranking of agents known. Industry is therefore left to figure out what countermeasure the government will be willing to fund next and how many doses will be needed. It is for this reason some believe the priority list of countermeasures should be publicized. However, there is concern if the priority list is publicized, terrorists will have a better understanding of vulnerabilities.

According to Jerome Donlon, chief scientist at HHS Office of Research and Development Coordination, "figuring out what to buy, and when, is more complicated than just moving down the select agent list. …decisions are based on material threat assessments conducted by the Department of Homeland Security. They factor in current intelligence data, the physical characteristics of the agents, plausible attack scenarios and the number of people who might be affected during the event." **(Attachment 2, p. 2)**

Questions remain about the usefulness of the DOD JVAP program in its current form. There are concerns the JVAP program overlaps the work of the NIAID. DynPort Vaccine Company is the prime contractor for the JVAP program and DynPort has also secured contracts with NIAID to

develop a vaccine for botulinum toxin and research on a vaccine for tularemia. **(Attachment 3)**

Project BioShield was created as a way to provide incentives to companies to develop medical countermeasures. However many companies feel BioShield didn't go far enough in providing incentives or liability protections.

Companies face several challenges when trying to develop medical countermeasures. These difficulties include being bounced around from agency to agency, and never receiving a clear commitment from the government to purchase their products. Even when a product is a known countermeasure, the challenge of getting a commitment from the government still remains. Intracel, a biopharmaceutical company, faced this problem when it attempted to sell the government a therapy for Botulinum toxin exposure. Even though the product was FDA approved for emergency use, the government did not offer any commitment to purchase the product.

Likewise, many companies have to put the development of their countermeasure on hold until they receive assurance from the government. Human Genome Sciences, a biopharmaceutical company, was in the process of developing a drug called ABthrax which would prevent and treat anthrax infections, however production was stopped since the company did not receive a commitment from the government to purchase their product.

The Subcommittee held a hearing on October 23, 2001 entitled, "Biological Warfare Defense Vaccine Research & Development Programs" where the biotechnology industry addressed concern regarding the risk and uncertainty of developing countermeasures without government funding. It appears industry is still faced with these challenges even after the enactment of BioShield.

2. **How is this process linked to validated threats?**

The Department of Homeland Security (DHS) Science and Technology Directorate (S&T) helps determine which agents constitute "material threats" and develops scenarios which help establish the quantity of countermeasures required. DHS has certified anthrax, smallpox, botulinum toxin, radiological/nuclear, and nerve agents as "material threats" and is currently conducting threat assessments for tularemia and plague.

DHS plans to have the rest of the Category A bioagents completed by FY 2006. **(Web Resource 8, p. 9)**

In FY 2006 the Department of Homeland Security (DHS) plans on completing the first formal risk assessment required under Homeland Security Presidential Directive-10 (HSPD-10). **(Web Resource 8, p. 4)** Some believe without the threat assessment it is difficult to move forward in protecting the nation from terrorist attacks since we can't be sure we have the necessary countermeasures in place. **(Attachment 4, p. 2)**

The National Science and Technology Council's Weapons of Mass Destruction Medical Countermeasures Subcommittee (WMD-MCM) provides an interagency forum for discussing and prioritizing medical countermeasure needs to be pursued under BioShield **(Web Resource 8, p. 8)**

DHS also works closely with HHS. This is noted in the following testimony by Mr. Stewart Simonson, Assistant Secretary for Public Heath Emergency Preparedness:

> Given an almost endless list of potential threats with finite resources to address them, prioritization is essential to focus our efforts. We rely heavily upon our interagency partner, the Department of Homeland Security, to provide us with a prioritized list of threats along with material decision making regarding how best to focus our National efforts in countermeasure development and acquisition, including whether in the short-term the so-called "one-bug, one-drug" approach should continue while simultaneously investing in more broad-spectrum prevention and treatment approaches for the longer term. **(Attachment 5, p. 3)**

Since it is difficult to predict the nature of the next terrorist attack, and science and technology may aid in the production of a new threat, agencies need to constantly re-examine their priorities. Mr. Simonson stated, "the number of threat agents against which we could guard ourselves is endless and new and emerging threats introduced by nature will present continuing challenges. Although we cannot be prepared for every threat, we have the ability to create a strategic approach to identifying and combating the greatest threats. HHS and its agencies including NIH, CDC, and FDA, have

a clear mandate from President Bush and Congress to lead the charge in this arena." **(Attachment 5, p. 3)**

With or without BioShield in place the successful development of medical countermeasures depends on the ability of agencies and industry to work together to meet goals in an efficient and effective manner.

Dr. Dale Klein, Assistant to the Secretary of Defense for Nuclear, Chemical and Biological Defense Programs will testify about the status of the Joint Vaccine Acquisition Program.

Dr. Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID) will testify about the role NIAID plays in developing countermeasures.

Mr. Stewart Simonson, Assistant Secretary for Public Health Emergency Preparedness, HHS will testify about the status of Project BioShield.

Mr. John Vitko, Director of Biological Countermeasures, Science and Technology Directorate, Department of Homeland Security will testify about the role DHS play in identifying, prioritizing and acquiring countermeasures.

Dr. Ronald Saldarini, Scientific Consultant, Institute of Medicine, will testify about the findings and recommendations from the IOM report entitled, "Giving Full Measure to Countermeasures: Addressing Problems in the DOD Program to Develop Medical Countermeasures Against Biological Warfare Agents."

Dr. Michael G. Hanna Jr., Chief Scientific Officer, Intracel will testify about the challenges he experienced in trying to sell the government a countermeasure for Botulinum toxin exposure.

Dr. James H. Davis, Executive Vice President and General Counsel, Human Genome Sciences will testify about the challenges his company has faced in trying to develop their countermeasure to anthrax.

ATTACHMENTS

1. *Giving Full Measure to Countermeasures: Addressing Problems in the DoD Program to Develop Medical Countermeasures Against Biological Warfare Agents,* Institute of Medicine Report, 2004.

2. Sean Madigan, "Biodefense Industry Grumbling Over HHS Handling of Germwar Priorities," *CQ Homeland Security,* May 23, 2005.

3. Congressman Christopher Shays February 18, 2005 letter to Secretary Rumsfeld and DOD March 22, 2005 response letter.

4. David Ignatius, "We're Unprepared: America is still vulnerable to a biological attack,"*Washington Post* May 20, 2005

5. Testimony of Stewart Simonson, Assistant Secretary for Public Health Emergency Preparedness before the Committee on Senate Appropriations Subcommittee on Homeland Security, April 28, 2005.

WEB RESOURCES

1. HHS News Release October 7, 2004
   http://www2.niaid.nih.gov/newsroom/releases/biod.htm

2. CDC Website Bioterrorism Agents/Disease
   http://www.bt.cdc.gov/agent/agentlist-category.asp#adef

3. NIAID News Release, May 10, 2005
   http://www2.niaid.nih.gov/Newsroom/Releases/bioshield.htm

4. JPM Chemical Biological Medical Systems Website
   http://www.jpeocbd.osd.mil/page_manager.asp?pg=2&sub=28

5. HHS Project BioShield Press Release, July 21, 2004
   http://www.hhs.gov/news/press/2004pres/20040721b.html

6. President Bush Details Project BioShield
   http://www.whitehouse.gov/news/releases/2003/02/print/20030203.html

7. Project BioShield Procurement Awards
http://www.hhs.gov/ophep/bioshield/bioshieldpr.html

8. Testimony of Dr. Penrose C. Albright, Assistant Secretary for Science and Technology, Department of Homeland Security before the Committee on Appropriation, April 28, 2005
http://appropriations.senate.gov/hearmarkups/STSACTestimony(04-28-05).pdf

Committee on Government Reform
Subcommittee on National Security, Emerging Threats, and International Relations
"Elusive Antidotes: Progress Developing Chemical Biological Radiological and Nuclear (CBRN) Countermeasures"
(June 14, 2005)
Witness List

PANEL ONE

Dr. Dale Klein
Assistant to the Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
Department of Defense

Dr. Anthony S. Fauci
Director, National Institute of Allergy and Infectious Disease (NIAID)
National Institute of Health

Mr. Stewart Simonson
Assistant Secretary for Public Health Emergency Preparedness
Department of Health and Human Services

Mr. John Vitko, Jr.
Director of Biological Countermeasures
Science and Technology Directorate
Department of Homeland Security

Dr. Ronald Saldarini
Scientific Consultant
Institute of Medicine

PANEL TWO

Dr. Michael G. Hanna Jr.
Chief Scientific Officer
Intracel

Dr. James H. Davis
Executive Vice President and General Counsel
Human Genome Sciences, Inc.